Title

United States
Securities and Exchange Commission, Washington D.C. 20549

Form 8-K

Elanco Animal Health Incorporated

Data Requirements

N/A

Author

Young T

Conducting Laboratory

N/A

Date Completed

May 7, 2021

Sponsored/Submitted by

Elanco US Inc.

Study or Report ID

ID-048182en

GOOD LABORATORY PRACTICES COMPLIANCE STATEMENT

The information contained in this report has been prepared in accordance with good and acceptable scientific practices. Because the information contained in this report is a discussion and assessment, and is not a study, compliance with GLPs is not applicable.

Company: Elanco US Inc.

Company Agent: Jennifer Schofield Digitally signed by Jennifer Schofield Date: 2021.05.23 12:45:20 -05'00'

Jennifer Schofield, DVM, CPH

STATEMENT OF DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA sec. 10(d)(1)(A), (B), or (C).

Company: Elanco US Inc.

Company Agent: Jennifer Schofield Digitally signed by Jennifer Schofield Date: 2021.05.23 12:45:46 -05'00'

Jennifer Schofield, DVM, CPH

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): **May 7, 2021**

Elanco Animal Health Incorporated

(Exact name of registrant as specified in its charter)

Indiana	**001-38661**	**82-5497352**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

2500 Innovation Way **Greenfield, Indiana** (Address of principal executive offices)	**46140** (Zip Code)

Registrant's telephone number, including area code: **(877) 352-6261**

Not Applicable
(Former Name or Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, no par value	ELAN	New York Stock Exchange
5.00% Tangible Equity Units	ELAT	New York Stock Exchange

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

☐ Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure

Elanco Releases Information Confirming Seresto Flea and Tick Collar's Strong Safety Profile

- *Case Does Not Equal Cause: In This Document, the Company Publicly Releases Third-Party Reviewed Data Analysis Concluding No Evidence of a Causal Link Between the Active Ingredients in Seresto and Pet Deaths*
- *Contrary to Media Reports, Active Ingredients in Seresto Extensively Studied Together*
- *Survey Indicates Consumer, Veterinarian Confidence in Seresto Remains High*
- *Company Continues to Engage with EPA and House Subcommittee to Provide Comprehensive Data*
- *Amid Misleading Media Stories, Company Driving Transparency to Ensure Consumers Understand Seresto's Strong Safety Profile*

Greenfield, Ind. (May 7, 2021) – Elanco Animal Health, Inc. (NYSE: ELAN) today is publicly providing data and information in this document recently shared with the Environmental Protection Agency ("EPA") and the United States House of Representatives Subcommittee on Economic and Consumer Policy (the "subcommittee"), as well as a new third-party assessment, to correct misinformation spread through some media reports regarding its Seresto flea and tick collar. The comprehensively reviewed adverse event data further demonstrates why the product's strong safety profile has earned registration from more than 80 regulatory bodies around the world and the trust of pet owners who have purchased more than 75 million collars globally to protect their pets from fleas and ticks.

"As pet owners ourselves and a company full of people who understand the unique bond our customers share with their pets, everyone at Elanco works tirelessly to make high-quality, safe, and effective medicines - and we are greatly concerned anytime someone believes they have had a negative experience with one of our products," said Jeff Simmons, president and chief executive officer at Elanco. "I can say with great conviction Seresto has a strong safety profile that protects millions of dogs and cats against potentially harmful fleas and ticks, which can transmit dangerous disease and impact pets' quality of life. I believe it is important to publicly release data Elanco shared directly with regulators and legislators and a new third-party assessment to help bring clarity to the misinformation in the media."

Data Analysis Concludes No Scientific Evidence of a Causal Link in Seresto's Active Ingredients and Pet Deaths

Elanco takes product stewardship and safety seriously and intentionally casts a wide net in gathering safety and efficacy data from pet owners and veterinarians when products go to market. Once a report is made, a medically trained team investigates each report to better assess and understand its cause. Elanco's team of experts trained in the science of pharmacovigilance thoroughly review and analyze the report data on an ongoing basis, along with reviews from outside experts and regulatory authorities. Data are periodically monitored for signals or trends to determine any concerns that need further evaluation.

Since Seresto's launch in 2012 through 2020, more than 28.5 million collars have been distributed across the U.S. Over this period, 12 pets—or 0.000042%—have reportedly died in a manner probably or possibly causally related to the Seresto collar. None of these were linked to the active ingredients in Seresto.

In the U.S., from product launch through the end of 2020, 1,852 reports were recorded where the Seresto collar was mentioned alongside the death of a pet. Consistent with the standard pharmacovigilance process, each event was investigated and assessed according to the ABON system, a recognized method of harmonizing causality assessments for adverse events to veterinary medicinal products.[1] Using this assessment outlined below, the following information details the 12 cases determined to be Probable (A) and Possible (B). The balance of the remaining reports were assessed to be in the O, N, and NA categories.

ABON System:
A = Probable – it is deemed probable that the product is causally related to the reported event
B = Possible – it is deemed possible that the product is causally related to the reported event
O = Unclassifiable/Not assessable – there is not enough information available to discern a causal relationship
N = Unlikely – it is deemed unlikely that the product is causally related to the reported event
NA = No Assessment – no assessment was completed as in cases of reported events that were nullified or for those involving a confirmed counterfeit product

[1] *Guideline on Harmonising the Approach to Causality Assessment for Adverse Reactions to Veterinarian Medicinal Products*, Committee for Veterinary Medical Products, The European Agency for the Evaluation of Medicinal Products, (2004) https://www.ema.europa.eu/en/documents/scientific-guideline/guidelineharmonising-approach-causality-assessment-adverse-reactions-veterinary-medicinal-products_en.pdf

ABON Code	Number of Reports	Analysis
A – Probable	**5**	• The result of entrapment concerning external structures, where the collar caught on an object and resulted in harm to the animal.
B – Possible	**7**	• Five cases were determined to be oral entrapments, where the collar got caught in the jaws of the animal resulting in harm. • Two consisted of a case of a tightened but not entrapped collar for one dog and a case of hypersalivation, seizure and death for another dog as reported by the owner, but without any summary from an attending veterinarian.

A third-party assessment of the 12 cases was also performed by toxicology, pathology, and veterinary pharmacovigilance expert Dr. Kevin Woodward, principal consultant at KNW Animal Health Consulting and Fellow Chartered Chemist of the Royal Society of Chemistry. Dr. Woodward's findings concur with Elanco's assessment, noting two cases where Elanco assessments were more conservative than his own assessment. Further, Dr. Woodward concluded that 11 out of 12 incidents were physical in nature and not related to the active ingredients of Seresto, adding that these numbers are in-line with similar incidents for non-medicated collars. In the remaining report, there is insufficient evidence to support a causal link between the incident and the active ingredients or other components in Seresto.

Every employee at Elanco understands the significant loss these pet owners feel and is deeply disappointed when an adverse event or reaction associated with any product occurs. Elanco continues to carefully monitor and analyze the data, as well as all other incident reports it receives.

The Active Ingredients in Seresto Were Studied Extensively and Together

Contrary to false media reports, the active ingredients in Seresto collars – flumethrin and imidacloprid – have been widely studied together, as required by the regulatory process in the U.S. and around the world.

In initial safety testing of Seresto collars to gain EPA approval, doses of 5x the recommended unit dosage were given to different animals for up to the eight-month application period. The only treatment-related side effects were mechanically induced hair thinning from collars rubbing the neck, mostly in animals that wore multiple collars. These side effects were resolved without therapy. Further, when applied per product label, the systemic levels of the active ingredients remain well below the No Observed Adverse Effect Level (NOAEL). This is well below any systemic exposure reasonably expected to cause systemic toxic effects.

The combination of flumethrin and imidacloprid specifically enables protection against a broad range of ectoparasites (parasites that live on the skin as opposed to within the body). Flumethrin is an acaricidal active ingredient, which means it targets arachnids such as ticks and mites. Imidacloprid is an insecticidal active ingredient, which means it targets insects such as fleas and lice. Together, these active ingredients provide protection against ticks, fleas, lice, and other ectoparasites, which can be vectors for disease, potentially leading to sickness and even death in pets, or in humans through zoonotic transmission.

Proper protection for pets will be especially critical during 2021, as forecasters predict that most states in the U.S. will experience warmer, wetter conditions that drive increased tick populations, likely putting ticks in range of people for much longer than in an average year.

Elanco Providing Comprehensive Data to the EPA

In the U.S., EPA conducts registration review on all registered pesticides, including the active ingredients in Seresto.

In accordance with regulatory requirements, Elanco provides reported incident data to the EPA on a regular basis, the EPA analyzes the data, and periodically reviews the data with Elanco. The company also analyzes incident data itself, continually monitoring for possible signals or trends. If a trend or signal is identified, Elanco investigates to determine if there is a causal link with the product and if so, takes appropriate action, including engaging with regulatory authorities. As part of this work, Elanco has from time-to-time engaged third-party pharmacovigilance and toxicological experts to independently review the data and compare the findings to the company's analysis. This robust review – by the EPA, by Elanco and by third-party experts –validates the product's safety profile.

Since Seresto's U.S. regulatory approval in 2012, data have been shared with EPA as required by regulation on the safety profile and efficacy of the product. Each time, case data was found to support the on-going use of Seresto. This has also been concluded by two independent analyses, supporting the positive benefit-risk balance. Furthermore, the number and rate of incident and death reports are not unique for Seresto and are in-line with other antiparasitic active ingredients.

Over the past few weeks, Elanco has held in-depth discussions with a broad team at the EPA to review reporting and data analysis on the safety profile of Seresto. Elanco has and will continue to provide a summary of Elanco pharmacovigilance processes, in-depth case information, causality assessments, qualitative and quantitative evaluations of the case information, as well as supporting data and information utilized in these analyses. Elanco will also provide its recently conducted expert reports based upon independent analysis of the data.

Additionally, as a globally marketed product, more than 80 other regulatory authorities around the world have reviewed the safety data collected over the course of Seresto's development prior to registration. Many regulatory authorities also require post-approval monitoring and pharmacovigilance reporting. All reviews to-date have indicated that the benefit-risk balance remains positive for Seresto.

Data Provided to Chairman of House Subcommittee on Economic and Consumer Policy
In March, the company received a letter from U.S. Rep. Raja Krishnamoorthi, chairman of the House Subcommittee on Economic and Consumer Policy, requesting the production of certain documents and information in connection with the Seresto collar. With a shared interest in protecting the health and well-being of pets and their owners, Elanco shared information with the subcommittee to set the record straight in the face of incorrect media reports. The company provided a summary of the safety data cited above, its pharmacovigilance process, and the regulatory framework behind the product by the requested March 31 deadline. Elanco continues to actively cooperate with the subcommittee to fulfill its request for information.

Research Shows Veterinarians and Consumers Remain Confident in Seresto
In light of misinformation about Seresto, Elanco launched market research to assess veterinarian and consumer confidence in the product to find the best ways to provide pet owners with correct and accurate information on Seresto's safety profile.

Of the 1,500 U.S. pet owners surveyed the week of April 23, 2021, 98 percent of Seresto users surveyed said they intend to repurchase the product. 97 percent of flea and tick category users surveyed could not recall negative Seresto news over the prior four weeks.

A similar representative national sample of 246 veterinarians found that while about half of veterinarians are familiar with the negative press coverage of Seresto, their reported use of the product and intent to recommend has not considerably changed.

Elanco has taken steps to ensure consumers understand Seresto's strong safety profile, including:

- Sharing additional education and accurate information through social and traditional media channels to 20,000 veterinary clinics
- Implementing enhanced in-store and online retailer advertising and accelerated marketing efforts to convey Seresto's strong safety profile
- Offering hands-on educational and training opportunities for up to 90,000 U.S. in-store retail associates
- Conducting outreach to veterinary and toxicology associations to share accurate product data
- Sharing Seresto safety profile and facts within targeted social and online channels

Importantly, Seresto remains available to consumers in all channels and at authorized retailers.

The Facts Support Seresto's Strong Safety Profile
As a global leader in animal health, Elanco understands and recognizes the deep bond that pet owners share with their pets, and will continue to work tirelessly toward the constant goal of enhancing and extending pets' quality of life through high-quality, safe medicines. As with all of Elanco's products, the company will continue to take actions to ensure the strong safety profile of the Seresto collar.

About Elanco
Elanco Animal Health Incorporated (NYSE: ELAN) is a global leader in animal health dedicated to innovating and delivering products and services to prevent and treat disease in farm animals and pets, creating value for farmers, pet owners, veterinarians, stakeholders, and society as a whole. With nearly 70 years of animal health heritage, we are committed to helping our customers improve the health of animals in their care, while also making a meaningful impact on our local and global communities. At Elanco, we are driven by our vision of Food and Companionship Enriching Life and our Elanco Healthy Purpose™ ESG/Sustainability framework – all to advance the health of animals, people and the planet. Learn more at www.elanco.com.

Forward Looking Statements

This filing may include certain statements concerning expectations for the future that are forward-looking statements as defined by federal securities law, including statements relating to the safety of Elanco's products, status of their regulatory approvals, actions to be taken by Elanco with regulatory agencies, and expected consumer and veterinarian behavior. Such forward-looking statements are subject to a variety of known and unknown risks, uncertainties, and other factors that are difficult to predict and many of which are beyond management's control. In particular, the expectations could be affected by, among other things, the uncertainties inherent in research relating to product safety and additional analyses of existing safety data, actions by regulatory bodies, including as a result of their interpretation of studies on product safety, unfavorable publicity resulting from media reports on our products, public acceptance of our products, and other risks and assumptions that are described in Elanco's annual reports on Form 10-K and other reports that are available from the U.S. Securities and Exchange Commission. Readers are cautioned not to place undue reliance on forward-looking statements, which reflect management's view only as of the date made. We undertake no obligation to update any forward-looking statement, except as otherwise required by law.

The information in this Form 8-K is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended ("Exchange Act"), or otherwise subject to the liabilities of that Section and shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended, or the Exchange Act, except as otherwise expressly stated in such filing.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Elanco Animal Health Incorporated

Date: May 7, 2021

By: /s/ Todd Young
Name: Todd Young
Title: Executive Vice President and Chief Financial Officer